

K253236 G-BLOCK

Sep 29, 2025

K253236 · Product code: **EBF** · DentalSource: <https://www.510kdatabase.net/k253236/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Material, Tooth Shade, Resin (EBF)
Date received	Sep 29, 2025
Decision date	Sep 29, 2025
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Graphenano Dental S.L.
Location	Yecla, ES
Contact	Eva Navarro
510(k) history	2 submissions · 2 cleared · 2022-2025

REGULATORY CONSULTANT

Consulting firm	Third Party Review Group, LLC
Contact	Dave Yungvirt

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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Device record: <https://www.510kdatabase.net/k253236/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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